

The Biospecimen Pre-analytical Variables (BPV) Program

Summary (1024-character limit)

The Biorepositories and Biospecimen Research Branch (BBRB) at the National Cancer Institute (NCI) has sponsored various initiatives for conducting biospecimen research. Through these initiatives, NCI seeks to advance biospecimen science and improve research reproducibility by investigating how different biospecimen collection, handling and processing procedures affect biospecimen molecular profiles. BBRB is seeking collaborators to extend these studies.

NIH Reference Number

E-000-0001

Product Type

- Therapeutics
- Vaccines
- Diagnostics
- Research Tools

Keywords

• Biospecimen Research, Biorepository, Immunohistochemistry, Protein Expression, DNA Methylation

Collaboration Opportunity

This invention is available for licensing and co-development.

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Description of Technology

The Biorepositories and Biospecimen Research Branch (BBRB) at the National Cancer Institute (NCI) has sponsored various initiatives for conducting biospecimen research. Through these initiatives, NCI seeks to advance biospecimen science and improve research reproducibility by investigating how different biospecimen collection, handling and processing procedures affect biospecimen molecular profiles. BBRB is seeking collaborators to extend these studies.

The Biospecimen Pre-analytical Variables (BPV) Program was designed to systematically investigate the effects of individual pre-analytical variables on biospecimen quality



(https://biospecimens.cancer.gov/programs/bpv/default.asp). The BPV program collected solid tumor and plasma samples that were manipulated to allow evaluation of multiple pre-analytical variables. The results of these studies have been used to develop evidence-based protocols for optimal collection, processing, and storage of biospecimens. Accumulated data from these studies have been deposited into the NIH Database of Genotypes and Phenotypes (dbGaP)

(https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs001304.v1.p1), where it is now available through controlled access to the research community.

BBRB is seeking collaborators interested in working with the NCI to perform additional studies to evaluate how pre-analytical variables affect the molecular profiles of plasma and different tumor types using the biospecimens from the BPV program. Sample details are available at https://pbc.vai.org/bpv/. Examples of the types of analysis for potential collaboration include the following:

- 1. Performing immunohistochemistry to evaluate how pre-analytical variables affect the expression level of certain proteins
- 2. Determining how pre-analytical variables affect the detection of DNA methylation through targeted or genomic-wide approaches
- 3. Evaluating how pre-analytical variables affect the results of clinical diagnostic or prognostic assays

It is expected that collaborators would enter into a collaborative research agreement with NCI, and will have the necessary resources to test these biospecimens within the context of a specific and approved research project to determine the impact of specific variables on biospecimen quality and downstream molecular analysis.

For more information about the Biospecimen Pre-analytical Variables Program, please see: http://biospecimens.cancer.gov/programs/bpv/default.asp.

Co-Development Opportunities:

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Potential Commercial Applications

• The results of these studies have been used to develop evidence-based protocols for optimal collection, processing, and storage of biospecimens

Competitive Advantages

- In addition to biospecimens collected prospectively to suit the aims of the agreed upon study, selected
 collaborators will have access to BBRB's biospecimen science, informatics, ethical and legal expertise.
 Public products (e.g., SOPs, standards, guidelines, peer-reviewed manuscripts) derived from these
 collaborations will be developed and released to the research community
- The NCI reserves the right to enter into only those collaborations that, in its sole discretion, will most effectively advance the BBRB's mission. This collaborative announcement is not a funding mechanism



or a promise to enter into any specific agreement. Interested parties should contact Dr. Jeffrey Thomas (information above)

Development Stage

• Prototype

Patent Status

• Research Material: NIH will not pursue patent prosecution for this technology

Therapeutic Area

- Cancer/Neoplasm
- Infectious Diseases
- Immune System and Inflammation
- Eye and Ear, Nose & Throat
- Hormonal Systems, Endocrine, and Metabolic Diseases
- Cardiovascular Systems
- Gastrointestinal
- Kidney and the Genitourinary
- Musculoskeletal
- Reproductive
- Skin and Subcutaneous Tissue
- Metabolic Disease
- Central Nervous System